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09/685,823	10/09/2000	Ellen H. Filvaroff	P1834	4430

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EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/685,823	FILVAROFF, ELLEN H.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 20 December 2001.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,3-9,16-21,23-29,37 and 39-46 is/are pending in the application.

4a) Of the above claim(s) 17,19,20 and 41-44 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,3-9,16,18,21,23-29,37,39,40,45 and 46 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1,3-9,16-21,23-29,37 and 39-46 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .	6) <input type="checkbox"/> Other: _____

## **DETAILED OFFICE ACTION**

Applicant's amendment in paper No. 8, filed on 20 December 2001 is acknowledged and entered. Following the amendment, claims 1, 9, 21, 29 and 37 are amended, claims 2, 10-15, 22, 30-36 and 38 are canceled, and the new claims 45 and 46 are added.

Currently claims 1, 3-9, 16-21, 23-29, 37, 39-46 are pending, and claims 1, 3-9, 16, 18, 21, 23-29, 37, 39, 40, 45 and 46 are under consideration.

### **Withdrawal of Objections and Rejections:**

All objections and rejections of claims 2, 10-15, 22, 30-36 and 38 are moot as the applicant has canceled the claim.

The objection of claims 1, 3-9, 16, 18, 21, 23-29, 37, 39, 40 for encompassing a non-elected subject matter is withdrawn in view of applicant's amendments.

The scope rejection of claims 6, 7, 26, and 27 under 35 U.S.C. 112, first paragraph is withdrawn in view of applicant's amendments.

The rejection of claims 1, 3-9, 21, 23-29, 37, 39, 40 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendments.

The rejection of claims 1-9, 13, 14, 21-26, 28, 29, 33, 34, and 37-40 under 35 U.S.C. 102(a) as being anticipated by Troutt (WO 98/23284) is withdrawn in view of applicant's amendments.

The rejection of claims 7 and 27 under 35 U.S.C. 103(a) as being unpatentable over Chabaud et al. (J. Immunol., 1998, 161:409-414), in view of Carroll et al. (Inflammation Research, 47:1-7, 1998) is withdrawn in view of applicant's argument.

### **Formal Matters:**

The applicant canceled claims 2, 10-15, 22, 30-36 and 38, as indicated in page 7 of the response. However, the canceled claims numbers are incorrectly indicated at page 11, lines 1-2, which recites that claims 2, 10-16, 22, and 30-36 have been canceled, and at page 12, lines 11-12, which recites that claims 2, 10-18, 22, 30-36 and 38 have been canceled. Clarification is required. Claims 2, 10-15, 22, 30-36 and 38 are considered canceled in the present Office Action.

Claim 16 is objected to for depending on a canceled claim, claim 15. The applicant is required to amend the claim to read only upon the pending claims, or to be an independent claim.

Claim 18 is objected to for encompassing non-elected subject matter. The applicant is required to amend the claims to read only upon the elected species, IL-1ra.

**Objections and Rejections under 35 U.S.C. 112:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 18 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons cited in the last Office Action, paper No. 6, mailed on 20 June 2001, at page 5.

Claims 9 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 29 recites the limitation "the antagonist" and "the IL-17 antagonist", respectively, in line 1. There is insufficient antecedent basis for these limitations in the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 8, 9, 16, 18, 21, 23-25, 28, 29, 37, 39, 40 remain rejected under 35 U.S.C. 112, first paragraph, as specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, for the reasons cited in the last Office Action, paper No. 6, mailed on 20 June 2001, at pages 3-5.

Applicants arguments, filed on 20 December 2001 (paper No. 8) have been fully considered, but is not deemed persuasive for reasons below.

At page 3 of the response in paper No. 8, the applicant indicates that the amended claims render the application of the rejection moot (lines 3-6 from the bottom of the page). However, the Examiner does not agree because the scope of the amended claims still includes any or all IL-17 mediated, inflammatory cartilaginous disorders. While the specification provides support for the treatment of RA and OA with the claimed method, it provides no evidence that such treatment is beneficial to *any or all* of inflammatory cartilaginous disorders, and the applicant's response does not address this issue. As so, the scope rejection of these claims under 35 U.S.C. 112, first paragraph is retained.

**Rejections Over Prior Art:**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3, 4, 8, 9, 21-26, 28, 29, 37, and 39 remain rejected, and claims 5, 6, 40, and 45 are under 35 U.S.C. 102(a) as being anticipated by Shigeru et al., JP2000186046 (July 4, 2000) for the reasons cited in the last Office Action, paper No. 6, at page 6.

Applicants argument, filed on 20 December 2001 (paper No. 8) has been fully considered, but is not deemed persuasive for reasons below.

At page 13 of the response, the applicant argues that the effective date of the reference is July 4, 2000, while the effective priority date of the present invention is at least May 14, 1999. This argument is not persuasive because the priority document does not contain subject matter which was described in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention of the present application. The priority document merely suggests that IL-17 likely contributes to loss of articular cartilage in arthritic joints, and thus inhibition of its activity might limit inflammation and cartilage destruction, and speculates that antagonists to IL-17 may be useful for the treatment of inflammatory conditions and cartilage defects such as arthritis. However, it provides no guidance or predictive teachings as to how to use the present invention. Therefore, the Examiner is not able to establish that the

priority document satisfies the enablement and description requirements of 35 U.S.C. 112, first paragraph (see MPEP 706.02(b), part (E)). As such, the claims of the instant application are not entitled to the benefit of the filling date of prior application SN09/380,142, and the reference by Shigeru still applies because the effective date of the reference is prior to the filling date of the present application.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-6, 8, 9, 21, 23-26, 28, 29, 37, 39, and 40 remain rejected, and claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chabaud et al. (J. Immunol., 1998, 161:409-414), in view of Carroll et al. (Inflammation Research, 47:1-7, 1998) for the reasons cited in the last Office Action, paper No. 6, at pages 7-8.

The teachings of Chabaud and Carroll were reviewed in the last Office Action.

Applicants argument, filed on 20 December 2001 (paper No. 8) has been fully considered, but is not deemed persuasive for reasons below.

At page 14 of the response, the applicant argues that Chabaud only indicates that "control of the production and action of IL-17 may represent a therapeutic target for reducing the enhancing effect of monocyte-derived cytokines", and that there is no suggestion that such cytokines might be responsible for IL-17 mediated inflammatory disorders (the third paragraph). The applicant further argues that Carroll does not mention that IL-17 or its effect on IL-17 mediated inflammatory disorders (the fourth paragraph). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where

there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, even though either Chabaud or Carroll teaches directly a role of IL-17 in a cartilaginous disorder or to use anti-IL-17 antibody for the treatment *in vivo*, suggestion or motivation to do so can be found based on combinations of references, which teach that anti-IL-6 antibody has therapeutic effect in RA patient (by Carroll), and that IL-17 increases the production of IL-6, therefore, control of the production and action of IL-17 may represent a therapeutic target for reducing the enhancing effect of monocyte-derived cytokines (by Chabaud). It is very clear, from the references, that IL-6 and IL-17 are elements in the same cascade events. Therefore, it is logical and obvious to a skilled artisan to control the action of IL-17, and to expect therapeutic effect in individuals with disorders such as RA, and using an antibody to block the function of a protein is the common practice and knowledge generally available to one of ordinary skill in the art.

Claims 1-4, 8-9, 13, 14, 21-26, 28, 29, 33, 34, and 37-39 remain rejected, and claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kotake et al. (J. Clin. Invest., 1999, 103:1345-1352), and Chabaud et al. (Arthritis & Rheumatism, 1999, 42:963-970), in view of Carroll et al. (Inflammation Research, 47:1-7, 1998) for the reasons cited in the last Office Action, paper No. 6, at page 8, and for the same reasons above, as the traversal is on the same ground as that above.

With respect to the argument that the prior art does not appreciate that a common cytokine, IL-17, can mediate cartilage damaged from both OA and RA (page 16, the fourth paragraph), the pertained claims, i.e. claims 7 and 27 were not included in the instant rejection.

Claims 16 and 18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Chabaud et al. (1998), and Arend et al. (Annu. Rev. Immunol., 1998, 16:27-55) for the reasons cited in the last Office Action, paper No. 6, at page 9.

Claims 1, 3-9, 21, 23-29, 37, 39, 40, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Troutt (WO 98/23284), in view of Carroll et al. (Inflammation Research, 47:1-7, 1998).

The teachings of Troutt and Carroll were reviewed in the last Office Action. Additionally, Troutt teaches that IL-17 upregulates release of nitric oxide (NO), which is involved in pathophysiological conditions of RA and OA, and that inhibitors of IL-17 will be useful in regulating levels of NO, and such inhibitors will find therapeutic application in ameliorating the effects of NO in OA, as well as autoimmune and inflammatory diseases (page 1, the first paragraph, and page 2, the third paragraph).

Troutt does not teach to apply anti-IL-17 antibody for the treatment of a cartilagenous disorder. Carroll teaches an anti-IL-17 antibody can antagonize IL-17 induced production of IL-6 and LIF, indicating that an antibody specific to IL-17 can block the action of the cytokine.

Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to treat a patient with RA or Office Action (a cartilagenous disorder or a degenerative cartilagenous disorder of articular cartilage) by administering an effective amount of anti-IL-17 antibody, as Troutt has suggested that inhibitors of IL-17 will find therapeutic application in OA or RA, and Carroll has indicated that anti-IL-17 antibody can block the action of IL-17. One of ordinary skill in the art would have been motivated to do so at Troutt's suggestion for therapeutic application, and reasonably would have expected success because of the positive results from Carroll's experimentation.

With respect to the argument at page 14 of the response, that Chabaud teaches that cultures of osteoarthritic synovium did not contain IL-17 related activity, thus Chabaud teaches away from using IL-17 antagonists for the treatment of OA. This argument has been fully considered, but is not deemed persuasive because the lack of IL-17 related activity in cultures of osteoarthritic synovium does not automatically mean that IL-17 is not involved in OA. Therefore, the Examiner does not consider that the cited reference teaches away from applying IL-17 antagonists for OA.

**Conclusion:**

No claim is allowed.

**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*Gary L. Jiang*  
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DJ  
3/7/02